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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,633	07/08/2002	Wilhelm Ansorge	100564-00103	1909

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
RILEY, JEZIA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/049,633	ANSORGE ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/07/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *21-46* is/are withdrawn from consideration.

5)☒ Claim(s) *7 and 9* is/are allowed.

6)☒ Claim(s) *1-3,5,11,16,17,47 and 48* is/are rejected.

7)☒ Claim(s) *4,6,8,10,12-15 and 18-20* is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

1. Applicants' arguments, filed on 12/7/2004, have been approved and entered. They have been fully considered. The applicants amendments deleting the epoxide limitation in the claims overcome the rejection over Hogan and Lipshutz.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Objections

2. Claim 10 is objected to because of the following informalities: The Y denoting isocyanate and isothiocyanate groups should be deleted since said group have been deleted from independent claim 1 . Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the solid phase for hybridization assays,

does not reasonably provide enablement for determining the function of a gene or metabolism. The claims are broadly drawn to method for determining the function of genes and a method for determining metabolism, comprising contacting free biopolymers with the immobilized biopolymers on a solid phase and correlating the interaction with the function gene or with metabolism. In the embodiments of the methods claims there is no disclosure of negative controls or conditions for positive controls under which the immobilized biopolymer should be used, for the selection of immobilized biopolymers that are specific to the desired targets.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification in pages 9-10 states that the solid phase can for example be used to sequence nucleic acids, to examine the expression of genes, the function of genes and metabolism. Instant claims 47 and 48, are broadly claiming the use of the solid phase for determining function of a gene and metabolism of any nucleic acid or PNA or peptides or polypeptides or lipids or carbohydrates. There is no disclosure or working examples where it is disclosed specific compositions that could be used for said methods. There is no disclosure of how one will select any nucleic acids, nucleic acid analogues, PNA, peptides, polypeptides, lipids or carbohydrates to practice the broadly claimed methods. There is no disclosure of how the said methods are performed and how said correlations are made as there is no disclosure of method steps for said correlations and how said function of a gene and metabolism are assessed. There is not disclosure of what type of function or metabolism is determined.

A broad possible range for negative controls are possible and in order to enable the selection of useful biopolymers, there is a need to set forth which negative controls is (are) to be used. Is there one organism that would be the negative control or a panel of organisms that would be the negative controls? It is undue experimentation to collect biopolymer, among the unspecified great number of organism, to determine the ones that would be used to detect the target in order to practice the broad scope of claims 47 and 48. These leave the entire work of finding biopolymers and what type of disease to detect up to someone wishing to practice claims 47 and 48 which is undue experimentation. Stackebrandt et al. (Patent # 5,089,386) disclose nucleic acid fragment capable of hybridizing to rRNA of *Listeria monocytogenes* and not to rRNA of *Bacillus subtilis.* They show a probe development strategy comprising: (1)Identifying regions of rRNA which might be useful as a target sites for nucleic acid hybridization probes. (2) These nucleotides sequences were compared to one another and to other rRNA nucleotide sequences. (3) Testing each nucleic acid probe is required. (4) Then first generation probes are designed and several other consideration are taken in count such as the geometry of the probe itself and self complementarity for example. In aggregate, the set of probes will detect most or al Listeria and few or no non-listeria. Then the final step of probe design is to test the probes on real samples. (col.4 to col. 7). In col. 3, lines 6-19 the authors state that probes to Listeria rRNA target sequences which are sufficiently similar in a significant number of Listeria that one or a few probes can hybridize to the target region in those Listeria and are sufficiently different in most

non-Listeria rRNAs, that under some conditions where the probe(s) hybridize to Listeria rRNAs, they are not capable of hybridizing, or very poorly, to most non-Listeria rRNAs.

Therefore given the unpredictability of the art and the lack of guidance in the specification, it is the Examiner's position that one skilled in the art could not perform the method of the claims as broadly recited without undue experimentation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 3, 5, 11, 16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishida et al. (US 5,200,270).

Ishida discloses a carrier for a biologically active component for immunoassay or enzymatic reaction, and a process for its preparation. The bead constituting the core of the carrier is made of a thermoplastic resin which includes a polyolefin. Then, magnetically responsive powder is deposited on the resin beads. The magnetically responsive powder may be a powder of iron, tri-iron tetroxide, nickel, iron-cobalt, silicon steel or a soft ferrite of the formula MFe2 O4 wherein M is Mn, Zn, Ni, Cd, Cu, Mg, Sr or Ba having an average particle size of from 0.01 to 10 μm. Which is therefore viewed as the instant solid phase selected from metallic solid phases , oxidic solid phases and

metallic-oxidic solid phases. Then, a polymer is further coated on the magnetic resin beads for the purposes of preventing the magnetically responsive powder from falling off and binding a biologically active component such as antigens, antibodies or enzymes which is viewed to be inclusive of the biopolymers of instant claim 5. The magnetic resin beads have to be coated with a polymer having functional groups capable of binding such a biologically active component. For instance, when the beads are coated with a polymer having aldehyde groups, they react with amino groups of the antibodies, antigens or enzymes to form linkages of a Schiff base. (col. 3-4). Col. 12 shows that the magnetic beads had many aldehyde groups on their surfaces and anti-T4 monoclonal antibodies were immobilized utilizing these aldehyde group which is viewed as being inclusive of forming an array structure. An enzyme-labeled antigens were added and were subjected to the antigen-antibody reaction and the fluorescence intensity was measured. (example 11).

7. Claims 4, 6, 8, 10, 12-15, 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 7 and 9 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuesday, February 14, 2005

JEZIA RILEY
PRIMARY EXAMINER

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600